

SEP 2 0 1996

Ronald L. Wilson, Director Health Assessment Policy Staff Office of Health Affairs (HFY-20) Food and Drug Administration 5600 Fishers Lane, Room 11-44 UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Re: LIPOSORBER LA-15 System

FDA Docket No. 96E-0189

Dear Mr. Wilson:

Rockville, MD 20857

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 4,637,994, which issued January 20, 1987. The application was filed on April 19, 1996, under 35 U.S.C. § 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Hiram H. Bernstein

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